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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/749,980	12/27/2000	Elaine Lee	8600-0010	6822

23419 7590 05/28/2003

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EXAMINER	
BAXTER, JESSICA R	
ART UNIT	**PAPER NUMBER**
3731	14

DATE MAILED: 05/28/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

N.K.

Office Action Summary	Application No.	Applicant(s)	
	09/749,980	LEE, ELAINE	
	Examiner	Art Unit	
	Jessica R Baxter	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 May 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-11,14-17,19,21-32 and 34-36* is/are pending in the application.

4a) Of the above claim(s) *25-30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3-11, 14-17, 19, 21-24, 31, 32 and 34-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Objections

1. Claims 4, 21 and 23 are objected to because of the following informalities:

a. Regarding claim 4, write out all abbreviations. (i.e. change "PDGF" to --platelet derived growth factor (PDGF)--).

b. Regarding claims 4, 21 and 23, several typographical errors appear.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 34 and 35 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Correction is noted and the rejection is withdrawn.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent

by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1, 3, 4, 11, 14, 19, 21 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,980,550 to Eder et al.

Regarding claims 1, 3 and 4, Eder discloses a vaso-occlusive composition that includes a vaso-occlusive member selected from the group of one or more occlusive coils, one or more filters, one or more retention devices (column 3 lines 17-20), a thrombus stabilizing molecule (column 6 lines 38-41, inner coating), and a bioactive material in the form of cytokine VEGF (Column 5 line 64-Column 6 line 15 and Column 6 lines 38-48, inner and outer coatings).

Regarding claim 11, Eder discloses a device that has a bioactive material, a thrombus-stabilizing molecule or both the thrombus-stabilizing molecule and the bioactive material permanently bonded to the vaso-occlusive member (column 6 lines 38-48).

Regarding claim 14, Eder also discloses a vaso-occlusive composition that has been plasma treated (column 3 lines 60-61).

Regarding claims 19, 21 and 24, Eder discloses a method to occlude an aneurysm by administering the vaso-occlusive composition (column7 lines19-23 and lines 48-59) by administering the bioactive material VEGF.

6. Claims 1, 5, 6, 16, 19 and 22 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,096,052 to Callister et al.

Regarding claims 1, 5 and 6, Callister discloses a device that comprises a vaso-occlusive member (FIGS. 22 and 23 coil 53) and an additional material of copper (column 8 lines 20-28).

Regarding claim 16, Callister discloses a device that is microtextured by sandblasting (column 8 lines 13-15).

Regarding claims 19 and 22, Callister also discloses a method that administers the composition including copper to occlude a vessel (see claims 33-42 and column 8 lines 25-28).

7. Claims 1, 7, 8, 11, 17, 19 and 23 rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,800,507 to Schwartz.

Regarding claims 1, 7 and 8, Schwartz discloses a composition that includes a vaso-occlusive member (column 4 lines 64-67) and thrombus-stabilizing molecule Factor XIII (column 3 lines 43-44). A stent is considered to be a retention device.

Regarding 11 and 17, Schwartz discloses a composition that the material fibrin is adsorbed to the vaso-occlusive member (column 3 lines 60-64) and the vaso-occlusive member has a tie layer between the stent and the material fibrin (column 3 line 60 - column 4 line 4).

Regarding claims 19 and 23, Schwartz discloses a method that administers a vaso-occlusive composition including the thrombus-stabilizing molecule Factor XIII (column 3 lines 43-44) to a subject (column 4 line 64 - column 5 line 5).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwartz '507. Schwartz discloses the claimed device except for the use of plasminogen activator inhibitor-1 (PAI-1) or α_2-antiplasmin as the thrombus-stabilizing molecule. It is well known that Factor XIII, PAI-1 and α_2-antiplasmin may all be utilized to prevent a thrombus from breaking up. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to replace Factor XIII (column 3 lines 47-48) with PAI-1 or α_2-antiplasmin, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice.

10. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schwartz '507 in view of U.S. Patent No. 5,891,192 to Murayama et al. Schwartz discloses the claimed invention except for the vaso-occlusive member being subjected to ion implantation. Murayama teaches that ion implantation alters the surface properties of a metal implant such as thrombogenicity, endothelial cellular migration and adhesion, minimally increases the dimensions of the implant, and increases the fixation of a protein coating on the metal surface of the implant (see Column 3 lines 21-29). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the metal stent of Schwartz '507 to include the application of ion implantation in order to change the surface properties including thrombogenicity, endothelial cellular migration and adhesion, minimally increase the dimensions of the stent, and to increase the fixation of the protein on the surface of the metal stent.

11. Claims 31, 32, 35 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,690,666 to Berenstein et al. in view of WO 00/27445 to Boock et al.

Berenstein discloses a vaso-occlusive composition comprising a coil and a particulate liquid embolic material (Column 5 line 66-Column 6 line 9). Berenstein does not disclose an additional

bioactive material selected from the group consisting of at least one cytokine, extracellular matrix material, DNA, RNA, functional fragments of DNA and RNA and combinations thereof. Boock teaches that a bioactive material is attached to a vaso-occlusive coil in order to reduce friction, provide a therapeutic for local or blood borne delivery, or enhance thrombosis, coagulation or platelet activity (Page 11 line 17-page 14 line 17). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the composition of Berenstein with the bioactive material of Berenstein in order to reduce friction, provide a therapeutic for local or blood borne delivery, or enhance thrombosis, coagulation or platelet activity.

12. Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Berenstein et al. '666 in view of WO 00/27445 to Boock et al. as applied to claims 31, 32, 35 and 36 above, and further in view of Murayama et al. '192.

Berenstein, as modified, discloses the claimed invention except for the coil being absorbable. Murayama teaches that a coil may be made out of known absorbable or non-absorbable materials for implants (Column 2 lines 37-50). It would have been obvious to make the coil of Berenstein out of an absorbable material, as taught by Murayama, since it is well-known in the art to make implants out of either absorbable or non-absorbable materials.

Response to Arguments

13. Applicant's arguments filed May 14, 2003 have been fully considered but they are not persuasive.

Rejections based on Eder

Applicant argues that the claimed invention never includes a water-soluble coating. Examiner disagrees with this argument because the water-soluble coating of Eder discloses that it may contain

a cytokine. The claim calls for "a bioactive material selected from the group consisting of fibrin; polyethylene glycol derivatives; thrombin-coated gelatin granules; balloons coated with iron microspheres, trace metals, thrombus-stabilizing molecules, RNA, DNA and combinations thereof." The phrase "combinations thereof", indicates that more than one of these materials may be present. There is no limitation that places these materials in the same layer. Eder discloses two layers, one contains a cytokine (outer layer) the other contains a thrombus-stabilizing molecule (inner layer). Therefore, the rejection over Eder '550 is proper.

Rejections based on Callister and Schwartz

Applicant argues that Callister and Schwartz do not disclose the claimed device. Applicant asserts that "the Office has acknowledged that Callister and Schwartz do not anticipate the vaso-occlusive compositions as presently claimed". It is not completely understood what is meant by this argument. Although Callister and Schwartz were previously not applied to claim 18, that does not mean that Callister and Schwartz can not be applied to the limitation in claim 18.

Applicant argues that a stent is not a vaso-occlusive device. In the applicant's own specification, stents are pointed out as being used as vaso-occlusive devices (page 4 lines 19-20). A stent is a retention device.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica R Baxter whose telephone number is 703-305-4069. The examiner can normally be reached on M-F 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on 703-308-2496. The fax phone numbers for the organization

where this application or proceeding is assigned are 703-305-3590 for regular communications and 703-305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Jessica R Baxter
Examiner
Art Unit 3731

jrb
May 22, 2003

MICHAEL J. MILANO
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700